UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

DWYN HARBEN Plaintiff, v. ALLERGAN USA, INC., ALLERGAN SALES, LLC, ALLERGAN, INC., and SOFREGEN MEDICAL, INC. Defendants.	2:18-cv-01833-PBT

REPLY IN FURTHER SUPPORT OF THE MOTION TO DISMISS OF DEFENDANT SOFREGEN MEDICAL, INC.

MATTER BEFORE THE COURT

Defendant Sofregen Medical, Inc. ("Sofregen"), by and through its attorneys, White and Williams LLP, filed a 12(b)(6) Motion to dismiss Plaintiff's complaint[1] on the grounds that Sofregen did not owe Plaintiff a duty as a matter of Pennsylvania law. Because Sofregen neither manufactured nor sold the SERI Mesh implanted in Plaintiff's breast, Sofregen cannot be held liable for Plaintiff's injuries under any theory.

In response, Plaintiff erroneously argues that (1) Sofregen owed Plaintiff a duty to warn of the alleged dangers of SERI Mesh after Sofregen's acquisition in November 2016 and before December 28, 2016, the date Plaintiff alleges the SERI Mesh was removed from her body; and (2) Sofregen can be held liable under the "product line" exception to the general rule of non-liability for a company when the acquisition occurred after the sale of the product in question by

[1] Plaintiff alleges that she was injured by the use of SERI Surgical Scaffold Mesh ("SERI Mesh") in a breast reconstruction surgery she underwent on January 25, 2015. At the time, Allergan manufactured and sold the SERI Mesh. Sofregen purchased the SERI Mesh business from Allergan 20 months after the sale of the mesh used in this case.

the predecessor. Neither of these arguments have merit under Pennsylvania law. Accordingly, Plaintiff's claims against Sofregen should be dismissed in their entirety.[2]

LEGAL ARGUMENT

A. PENNSYLVANIA PRODUCT LIABILITY LAW DOES NOT IMPOSE A POST-SALE DUTY TO WARN ON A SUCCESSOR CORPORATION

Under Pennsylvania law, even the original manufacturer of a product owes only a very limited duty to warn purchasers of a danger in a product after the product has been sold. See Walton v. Avco, 610 A.2d 454 (Pa. 1992). Importantly, however, the original product manufacturer only has a post-sale duty to warn purchasers if the product manufacturer knew of the defect ***at the time it placed the defective product into the stream of commerce***. See id. at 463 (Papadakos, J., concurring). In other words, under Pennsylvania law, if, and only if, the product manufacturer had knowledge of an alleged defect at the time of sale, does it have a continuing obligation to warn consumers of potential danger (both at and after the time of sale). See id. Although Plaintiff alleges that ***Allergan*** knew of the alleged defect in SERI Mesh prior to the date of sale to Plaintiff and/or Plaintiff's surgeon, she admits that Sofregen did not know of any alleged defects in the product until it acquired SERI Mesh from Allergan in November 2016. See Plaintiff's Brief at 4. Accordingly, Sofregen did not owe Plaintiff a post-sale duty to warn under the narrow exception recognized in Walton.

Plaintiff incorrectly claims that even though Sofregen acquired SERI Mesh from Allergan nearly two years after her surgery, between November and December 2016 it owed her a duty to "advise either Plaintiff or her surgeon of the foreseeable risks associated with the SERI Mesh product or how best to mitigate the damage caused by the SERI Mesh . . . ." See id.

[2] If this Court does not dismiss Plaintiff's claims against Sofregen in their entirety for lack of a legal duty, Sofregen joins the motion to dismiss filed by Defendants Allergan, USA, Inc., Allergan Sales, Inc. and Allergan, Inc. (collectively, "Allergan") and requests that Plaintiff's claims against Sofregen be dismissed for all of the reasons asserted therein.

Plaintiff fails to cite ***any*** Pennsylvania authority which supports this proposition. Rather, she cites numerous cases from other jurisdictions which have little to no applicability to the issue of Sofregen's duty to warn of a danger it allegedly should have known about ***two years after Allergan*** sold the product at issue. See id.

The only case Plaintiff cites which even remotely addresses her arguments is the District Court opinion in Tracey v. Winchester Repeating Arms, Co., 745 F. Supp. 1099 (E.D.Pa. 1990). In that case, the court noted that ***other jurisdictions*** had recognized, in certain very specific circumstances, that a successor corporation may have a sufficient relationship with a customer who purchased a product from a predecessor to impose a duty to warn on the successor. See id. at 1112. Significantly, however, the District Court noted that, even in jurisdictions which recognize this potential basis for liability, it can only be established based on allegations that the successor corporation had an independent relationship with the ***specific purchaser*** of the product at issue (*i.e.*, the successor provided ongoing maintenance, service or repair to the product in the possession of the plaintiff). See id. The Tracey court further held that the mere allegation that the successor knew or should have known of the defective nature of the product was ***insufficient*** "to show the necessary relationship between the successor and the customers of the predecessor" to give rise to liability under this theory. See id. In this case, Plaintiff has not alleged any "independent relationship" with Sofregen following Sofregen's acquisition of SERI Mesh in November 2016; nor could she as Plaintiff's care was being managed by her surgeon and Plaintiff did not look to Sofregen for maintenance, service or repair of the medical device which had been implanted in her breast nearly two years earlier.

Plaintiff's citation to the non-binding memorandum opinion in Schwartz v. Abex Corp., 106 F.Supp.3d 626 (E.D.Pa. 2015) is likewise unavailing. In Schwartz, the District Court

endeavored to predict whether the Supreme Court of Pennsylvania would adopt the "bare metal defense" in asbestos litigation. Under the "bare metal defense," the seller of a product which it knew would be used with an asbestos-containing component could not be held liable in tort for resultant injuries if the product seller neither manufactured nor sold the asbestos-containing component. See id. at 628. In the narrow and specific context of asbestos litigation, the Schwartz court held that a manufacturer or supplier of a product had a duty to warn consumers of asbestos-related hazards attendant to aftermarket component parts it knew – ***at the time it placed its product into the stream of commerce*** – would be used in connection with its product. See id. In this way, Schwartz is consistent with Pennsylvania law regarding the limited post-sale duty to warn, imposing that duty only on a product manufacturer who knew of dangers related to a particular product (or aftermarket component parts that would foreseeably be used in connection with the product) ***at the time of sale***. In this case, based on Plaintiff's own allegations, Sofregen did not learn of any alleged defect in the SERI Mesh product until ***two years after*** the sale at issue.

Finally, Plaintiff erroneously suggests that federal law imposes an obligation on Sofregen to "monitor, investigate and report any and all post-market adverse events [associated with its medical device product.]" See Plaintiff's Brief at 6. As authority for this proposition, Plaintiff cites her own complaint and the ***dissent*** in Wyeth v. Levine, 555 U.S. 555, 608 (2009). See id. Not only is a dissenting opinion not binding on this court but, more significantly, the issues in Wyeth have no bearing on this case. Wyeth concerned the question of whether Federal Drug Administration ("FDA") approval of warnings and recommendations for a particular drug preempted a suit in tort predicated on an alleged failure to provide adequate warnings. The quoted language from the Wyeth dissent refers to a drug manufacturer's continuing obligation to

provide updated information to the FDA, rather than directly to consumers, and was stated in support of the position that the plaintiff's common law claims should have been deemed preempted by federal law. See Wyeth, 555 U.S. at 608. Nothing in the Wyeth opinion (majority or dissent) supports the proposition that a successor corporation, which neither manufactured nor sold the product at issue, has an affirmative obligation to investigate potential dangers associated with products made and sold before the acquisition.

B. BECAUSE PLAINTIFF HAS A REMEDY AGAINST ALLERGAN – THE PREDECESSOR CORPORATION WHICH ACTUALLY MANUFACTURED AND SOLD SERI MESH TO PLAINTIFF – THE "PRODUCT LINE EXCEPTION" CANNOT IMPOSE LIABILITY ON SOFREGEN

The central tenet of the "product line exception" to the general rule of non-liability for a successor corporation is that the exception only applies in cases where the general rule of successor non-liability would leave plaintiffs "***without a remedy when injured by defective products.***" See Indem. Ins. Co. of N. Am. v. Gross-Given Mfg. Co., 2009 U.S. Dist. LEXIS 84965, *8 (E.D. Pa. Sep. 16, 2009) (emphasis added) (citing Kradel v. Fox River Tractor Co., 308 F.3d 328, 331 (3d Cir. 2002)). Plaintiff incorrectly claims that the lack of an alternate remedy is merely a permissive factor which this court is free to disregard. See Plaintiff's Brief at 8.

In advancing this argument, Plaintiff ignores Kradel and other binding Third Circuit precedent to the contrary. Moreover, in support of the broad proposition that the "product line exception" is "multifactorial," Plaintiff cites the Third Circuit's unpublished opinion in McLaud v. Indus. Res., 715 Fed. App'x. 115 (3d Cir. Oct. 26, 2016). In that case, the court affirmed the dismissal of a claim against a successor corporation specifically because the company that originally manufactured the product at issue was a viable entity that could be sued. See id. at

119. In so holding, the McLaud court observed that "the first factor [of the multifactor "product line exception" test] (whether remedies are still available against the original manufacturer) is logically the most important [because it] reflects the public policy purpose of the product-line exception . . . ." Id. (internal citations omitted). Plaintiff fails to cite a single case (in Pennsylvania or elsewhere) where a court applied the "product line exception" when the plaintiff still had a viable remedy against the original product manufacturer. So too here, because Allergan, the original manufacturer of SERI Mesh, is not only a viable entity but has been sued in this matter, the "product line exception" is inapplicable to impose liability on Sofregen as a matter of law.

RELIEF

For the foregoing reasons as well as those set forth in Sofregen's motion to dismiss, which is incorporated herein by reference, Sofregen respectfully requests that this Honorable Court grant its motion and dismiss Plaintiff's claims against Sofregen, in their entirety, with prejudice. In the alternative, Sofregen joins in Allergan's motions to dismiss and requests dismissal of all claims against it for the reasons set forth therein.

Respectfully submitted,

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